

(3) Not for use in horses intended for food.¹

(4) Do not use in conjunction with organophosphates and/or procaine hydrochloride, because phenothiazines may potentiate the toxicity of organophosphates and the activity of procaine hydrochloride.¹

(5) Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[40 FR 13858, Mar. 27, 1975, as amended at 50 FR 41490, Oct. 11, 1985]

§ 522.2610 Trimethoprim and sulfadiazine sterile suspension.

(a)(1) *Specifications.* Each milliliter of sterile aqueous suspension contains 240 milligrams (40 milligrams of trimethoprim and 200 milligrams of sulfadiazine).

(2) *Sponsor.* See 000061 and 000856 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Dosage.* One milliliter (40 milligrams of trimethoprim and 200 milligrams of sulfadiazine) per 20 pounds (9 kilograms) of body weight per day.

(ii) *Indications.* For dogs for treatment of acute urinary tract infections, acute bacterial complications of distemper, acute respiratory tract infections, acute alimentary tract infections, and acute septicemia due to *Streptococcus zooepidemicus*.

(iii) *Limitations.* For subcutaneous use in dogs only; administer once every 24 hours, or for severe infections, after an initial dose, administer half the normal daily dose every 12 hours; continue therapy 2 to 3 days after clinical signs of infection have subsided; if no improvement is seen in 3 to 5 days, reevaluate diagnosis; injection may be used alone or in conjunction with oral dosing; not recommended for use for more than 14 days; a complete blood count should be done for prolonged use; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b)(1) *Specifications.* Each milliliter of sterile aqueous suspension contains 480 milligrams (80 milligrams of

these uses need not include the effectiveness data specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

trimethoprim and 400 milligrams of sulfadiazine (as the sodium salt)).

(2) *Sponsor.* See 000856 and 011716 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Dosage.* Two milliliters (160 milligrams of trimethoprim and 800 milligrams of sulfadiazine) per 100 pounds (45 kilograms) of body weight per day.

(ii) *Indications.* For horses where systemic anti-bacterial action against sensitive organisms is required during treatment of acute strangles, respiratory tract infections, acute urogenital infections, and wound infections and abscesses.

(iii) *Limitations.* For intravenous use; administer as single, daily dose for 5 to 7 days; daily dose may also be halved and given morning and evening; continue acute infection therapy 2 to 3 days after clinical signs have subsided; if no improvement of acute infections is seen in 3 to 5 days, reevaluate diagnosis; a complete blood count should be done periodically for prolonged use; not for use in horses intended for food; Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 241, Jan. 4, 1983, as amended at 48 FR 23180, May 24, 1983; 48 FR 42809, Sept. 20, 1983; 61 FR 5507, Feb. 13, 1996; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 522.2615 Tripeleppamine hydrochloride injection.

(a) *Specifications.* Each milliliter of aqueous solution contains 20 milligrams of tripeleppamine hydrochloride.

(b) *Sponsor.* See Nos. 053501 and 059130 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.741 of this chapter.

(d) *Conditions of use*—(1) *Amount*—(i) *Dogs, cats, and horses.* For intramuscular use only at a dose of 0.5 milligram per pound of body weight.

(ii) *Cattle.* Administer intravenously or intramuscularly at a dose of 0.5 milligram per pound of body weight.

(2) *Indications for use.* For use in treating conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease.

(3) *Limitations.* Do not use in horses intended for food purposes. Treated cattle must not be slaughtered for food